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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3993	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	~~3993~~ 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1,2,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000).

As to claim 1, Downs discloses a pressure-assisted breathing system comprising: a pressure-generating circuit (12,14) for maintaining a positive pressure (col.4, lines 34-45) within the system; a patient interface device (20 and col.3, lines 57-64) adapted to be coupled to a patient's respiratory system; a respiratory circuit (16) providing gas communication between the pressure-generating circuit and the patient interface device.

The difference between Downs and claim 1 is a nebulizer coupled to the respiratory circuit.

Berggren et al. in a CPAP system (fig.1), teach a nebulizer coupled to the respiratory circuit for the purpose of providing surfactant to newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival (page 460, col.1, lines 1-3).

It would have been obvious to modify the CPAP system of Downs to couple a nebulizer to the respiratory circuit because it would have provided surfactant to

newborns suffering from respiratory distress syndrome in order to improve alveolar gas exchange and thereby improve their chance of survival as taught by Berggren et al..

As to claim 2, Downs discloses the pressure-generating circuit (12,14) comprises a conduit that couples a flow generator (14) with a pressure regulating device (24) and the respiratory circuit (16) is connected to the conduit at a location between the flow generator and the pressure-regulating device (fig.1).

As to claim 20, Downs as modified by Berggren et al. as discussed above with respect to claim 1 also teach the pressure generating circuit (12,14 of Downs) having a higher volume flow of gas than the respiratory circuit (16 of Downs); coupling the patient interface (#20 and col.3, lines 57-64 of Downs); and introducing an aerosolized medicament only into the lower volume flow of gas in the respiratory circuit to deliver the medicament to the patient's respiratory system (fig.1 of Berggren et al.).

3. Claims 14,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) as applied to claim 1 above, and further in view of Isaacson ('798).

As to claim 14, Downs as modified by Berggren et al. as discussed above with respect to claim 1 also teach a first gas conduit (14 of Downs) connecting a flow generator (12 of Downs) to a pressure-regulating device (24 of Downs) to provide a first high volume gas flow for generating a continuous positive airway pressure (col.4, lines 34-45); a patient interface device (20 and col.3, lines 57-64 of Downs) adapted to be coupled to a patient's respiratory system; a second gas conduit (#16 of Downs) connected to a branch of a junction between conduits (14 and 16) and to the patient

interface device, whereby a portion of the first flow is diverted into said second gas conduit through the branch gas conduit, thereby providing a second gas flow to the patient's respiratory system that is lower volume than the first gas flow; and a nebulizer (fig.1 of Berggren et al.) coupled to the second gas conduit so as to emit an aerosolized medicament into the second gas flow. Downs expressly refers to conduit (16) as a conduit branch (col.3, lines 56-57) and since breathable gas also flows through conduit (14) to pressure regulator (24) a junction that connects conduits (14 and 16) is implicit; moreover, Downs expressly discloses a junction (26) between conduit (14) and pressure relief valve (24). To the extent, if any, that the connection between conduits (14 and 16) of fig.1 of Downs may not include a junction unit, resort is had to Isaacson which teaches a junction unit (42) for connecting a source of pressurized breathable gas to a patient interface device (10) and to a pressure regulating device (43). It would have been obvious to modify the conduits (14 and 16) of Downs to include any well known type of coupling including the junction unit (43) of Isaacson because it would have provided a quick connect/disconnect coupling thereby enabling a user to disconnect the conduits for storage, cleaning and repair as taught by Isaacson.

As to claim 17, while Berggren et al. are silent as to the particular weight of the nebulizer, it is submitted that the weight of the particular nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular weight including 5 gms or less. One of ordinary skill would have recognized that a nebulizer for infants would have required less medicament and therefore a smaller nebulizer weight. Further, the particular sound pressure levels

output by the nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular sound pressure level including 5dB or less. One of ordinary skill would have recognized the advantage if not need to employ a nebulizer that operates in a manner that does not wake a patient undergoing CPAP therapy during sleep.

4. Claims 3,4, are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) as applied to claims 1,2,20 above, and further in view of Fink et al. (Aerosol Drug Therapy).

The difference between Downs as modified by Berggren et al. and claim 3 is the pressure generating circuit comprising a first flexible tube and the respiratory circuit comprising a second flexible tube, and wherein the second flexible tube has a smaller diameter than the first flexible tube.

Fink et al. (figs.12-26 and 12-27), in a pressure assisted breathing system, teach a pressure generating circuit comprising a first flexible tube (see portion of corrugated tubing attached directly to the nebulizer) and a respiratory circuit comprising a second flexible tube (see portion of Y-shaped connected that is inserted within the corrugated tubing that is directly attached to the nebulizer), and wherein the second flexible tube has a smaller diameter than the first flexible tube. The use of corrugated tubing in the respiratory arts is well for its flexibility which permits patients to assume a variety of body positions and remain attached to the ventilator.

It would have been obvious to further modify the pressure generating circuit and respiratory circuits of Downs to employ any well known conduits including the

corrugated conduits because it would have provided flexibility which permits patients to assume a variety of body positions and remain attached to the ventilator as taught by Fink et al..

As to claim 4, the particular diameters of the corrugated tubing of Fink et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameters including 5mm or less. Tubing diameters would have depended upon the particular respiratory needs of a given patient; for example, an adult patient would require more pressure and flow rate than an infant and therefore larger capacity (i.e. diameter) conduits.

5. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) and Isaacson ('798) as applied to claim 14 above, and further in view of Fink et al..

The difference between Downs as modified by Berggren et al. and claim 15 is the pressure generating circuit comprising a first flexible tube and the respiratory circuit comprising a second flexible tube, and wherein the second flexible tube has a smaller diameter than the first flexible tube.

Fink et al. (figs.12-26 and 12-27), in a pressure assisted breathing system, teach a pressure generating circuit comprising a first flexible tube (see portion of corrugated tubing attached directly to the nebulizer) and a respiratory circuit comprising a second flexible tube (see portion of Y-shaped connected that is inserted within the corrugated tubing that is directly attached to the nebulizer), and wherein the second flexible tube has a smaller diameter than the first flexible tube. The use of corrugated tubing in the

respiratory arts is well for its flexibility which permits patients to assume a variety of body positions and remain attached to the ventilator.

It would have been obvious to further modify the pressure generating circuit and respiratory circuits of Downs to employ any well known conduits including the corrugated conduits because it would have provided flexibility which permits patients to assume a variety of body positions and remain attached to the ventilator as taught by Fink et al..

As to claim 16, the particular diameters of the corrugated tubing of Fink et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameters including 5mm or less. Tubing diameters would have depended upon the particular respiratory needs of a given patient; for example, an adult patient would require more pressure and flow rate than an infant and therefore larger capacity (i.e. diameter) conduits.

6. Claims 5-10,21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) as applied to claims 1,2,20 above, and further in view of Davison (GB 2 272 389).

The difference between Downs as modified by Berggren et al. and claim 5 a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit.

Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

While Berggren et al. is silent as to the particular type of nebulizer, it would have been obvious to employ any well known type of nebulizer including a vibrating aperture-type nebulizer because it would have facilitated the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose as taught by Davison et al..

As to claim 6, the reservoir of Davison et al. (page 2, lines 10-13) has a capacity equal to one unit dose of medicament.

As to claim 7, Davison et al. disclose a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claims 8-10, while Berggren et al. as further modified by Davison et al. are silent as to the particular weight of the nebulizer, it is submitted that the weight of the particular nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular weight including 5 gms or less. One of ordinary skill would have recognized that a nebulizer for infants would have required

less medicament and therefore a smaller nebulizer weight. Further, the particular sound pressure levels output by the nebulizer can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular sound pressure level including 5dB or less. One of ordinary skill would have recognized the advantage if not need to employ a nebulizer that operates in a manner that does not wake a patient undergoing CPAP therapy during sleep.

As to claim 21, Berggren et al. as further modified by Davison et al. (fig.2) teach the aerosolized medicament is introduced by a vibrating aperture-type nebulizer coupled to the respiratory circuit.

As to claim 22, Davison et al. teach the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

As to claim 23, Davison et al. disclose a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Berggren et al. as further modified by Davison et al. as discussed above with respect to claim 1 also teach a method of delivering surfactant medicament to a patient's respiratory system (Berggren et al.) and entraining the aerosolized surfactant into the respiratory circuit, whereby the patient breathes the aerosolized surfactant through the patient interface device (fig.2 of Davison et al.).

As to claim 25, Berggren et al. (page 461, col.1, lines 4-5) disclose the surfactant to be Curosurf which is a phospholipid.

As to claims 26 and 28, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient in Berggren et al. as further modified by Davison et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount including 6-18% and 10mg or less. Berggren et al. (page 461, col.1) disclose diluting surfactant prior to nebulization and Davison et al. teach a variable capacity reservoir (14) which controls the dose size; consequently, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Davison et al. teach the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) and Isaacson ('798) as applied to claim 17 above, and further in view of Davison et al..

The difference between Downs as modified by Berggren et al. and Isaacson and claim 18 is a nebulizer reservoir having a capacity equal to one unit dose of medicament.

The reservoir of Davison et al. (page 2, lines 10-13) has a capacity equal to one unit dose of medicament. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

While Berggren et al. is silent as to the particular type of nebulizer, it would have been obvious to employ any well known type of nebulizer including a vibrating aperture-type nebulizer because it would have facilitated the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose as taught by Davison et al..

8. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downs ('411) in view of Berggren et al. (Acta Paediatr 89: 460-4, 2000) as applied to claims 1,2,20 above, and further in view of Duarte et al. (Respiratory Care Clinics of North America 7:2, June 2001).

The difference between Downs as modified by Berggren et al. and claim 11 is the nebulizer being located in the direct vicinity of the patient's nose, mouth or artificial airway.

Duarte et al. (page 239) teach the nebulizer being located in the direct vicinity of the patient's nose, mouth or artificial airway (i.e. 30cm) for the purpose of improving aerosol delivery.

It would have been obvious to further modify the position of the nebulizer of Berggren et al. to locate it in the direct vicinity of the patient's nose, mouth or artificial airway because it would have improved aerosol delivery as taught by Duarte et al..

As to claim 12, fig.1 of Berggren et al. illustrates at least one gas conduit contained within the patient interface device (nasal mask) and the nebulizer is integral part (i.e. an essential element of the CPAP nebulization system of Berggren et al. as illustrated in fig.1) with the patient interface device.

As to claim 13, fig.1 of Berggren et al. illustrates the patient interface device comprising nasal prongs.

Response to Arguments

9. Applicant's arguments with respect to claims 1-18,20-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron J. Lewis
AARON J. LEWIS
Primary Examiner
Art Unit 3993

Aaron J. Lewis
October 01, 2006